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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,926	07/29/2005	Walter H. Hsu	08411-041US1	4316

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EXAMINER	
SWARTZ, RODNEY P	
ART UNIT	PAPER NUMBER
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,926	HSU ET AL.	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27December2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *34-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' Response to Office Action, received 27 December 2006, is acknowledged. Claims 1-33 have been canceled. New claims 34-60 have been added.

2. Claims 34-60 are pending and under consideration.

Rejections/Objections Moot/Withdrawn

3. The rejection of claims 1-33 under 35 U.S.C. 112, first paragraph, scope of enablement for any/all polypeptides from any/all sources with a molecular weight of about 30 to about 150 kDa, is moot in light of the cancelation of the claims.

4. The rejection of claims 1-27 under 35 U.S.C. 102(b) as being anticipated by Ross et al (WO95/09870) is moot in light of the cancelation of the claims.

5. The objection to Figure 5 is withdrawn in light of the replacement drawing.

6. The objection to Figure 11 is withdrawn in light of the replacement drawing.

New Rejections Necessitated by Amendment

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Newly added claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what new limitations are placed on the invention by this dependent claim because the polypeptide of claim 34 is obtained from a pathogenic *Mycoplasma hyopneumoniae.*

9. Newly added claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what new limitations are placed on the invention by this dependent claim because the polypeptide of claim 39 is obtained from a pathogenic *Mycoplasma hyopneumoniae.*

10. Newly added claims 53-60 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods utilizing porcine ciliated tracheal cells, does not reasonably provide enablement for methods utilizing any/all types of cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention in claims 53-56 is a method of identifying an inhibitor of mycoplasma induced calcium release in cells comprising contacting any cell with a mycoplasma

polypeptide which is know to increase calcium release from porcine ciliated tracheal cells in the presence of a test compound, and determining whether the test compound inhibits said unknown cell from releasing calcium.

The nature of the invention in claims 57-60 is a method of identifying an inhibitor of mycoplasma induced calcium release in cells comprising contacting any cell with a mycoplasma polypeptide which is know to increase calcium release from porcine ciliated tracheal cells pretreated with a test compound, and determining whether the test compound inhibits said unknown cell from releasing calcium.

The state of the prior art as evidenced by applicants' specification, and a computer search of the art produced applicants' own work utilizing a polypeptide obtained from a pathogenic *Mycoplasma hyopneumoniae* in assays of calcium release only with porcine ciliated cells. There is no evidence that any/all other types of cells from any/all other sources can be utilized in the calcium release assays utilizing a polypeptide obtained from a pathogenic *Mycoplasma hyopneumoniae*. Therefore, there is a lack of predictability in the art that any cell other than porcine ciliated tracheal cells can function as the indicator cells for the claimed assays.

The amount of direction/guidance/working examples present in the instant specification is focused solely on porcine ciliated tracheal cells and does not provide sufficient guidance/examples for the extremely broad scope of the instant claims, i.e., that any/all types of cells from any/all sources can be utilized successfully as the required indicators of calcium release.

11. Claims 34-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The newly added claims are now all drawn to a mycoplasma polypeptide of a pathogenic *M. hyopneumoniae* wherein said mycoplasma polypeptide increases calcium release form porcine ciliated tracheal cells.

It is unclear if the claimed polypeptide is only restricted to being present in the pathogenic *M. hyopneumoniae*, or can also be present in nonpathogenic *M. hyopneumoniae*. This question arises due to the specification teaching activity in both pathogenic and nonpathogenic forms, but that the pathogenic form exhibited two polypeptide bands not exhibited in the nonpathogenic form (Example 2).

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 34-52 are rejected under 35 U.S.C. 102(b) as being anticipated by Faulds (U.S. Pat. No. 5,240,706).

The claims are drawn to a substantially pure mycoplasma polypeptide of a pathogenic *M. hyopneumoniae*, antibody which binds to the polypeptide, method for inducing an immune response in a mammal by administration of said polypeptide, and a method of binding an antibody to said polypeptide. The physical characteristics of said polypeptide is that is be

between 10-80 kDa. An activity of said polypeptide is that is increase calcium release from porcine ciliated tracheal cells.

Faulds teach the polypeptides from the membrane of a pathogenic *M. hyopneumoniae* which have the physical characteristics of molecular weights between 10-80 kDa (Example 1), induce an immune response in an animal (Example 2, Antiserum; Example 6, vaccines), and bind to antibody in an antibody binding method (Example 2). While Faulds does not teach the calcium release activity of the instant claims, because the polypeptides are purified from the membrane of a pathogenic *M. hyopneumoniae*, and satisfy the molecular weight characteristics, immune response characteristics, the ability to alter calcium release in porcine ciliated tracheal cells is an inherent activity, in the absence of evidence to the contrary.

Conclusion

14. No claims are allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 7:30 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Jeffrey Siew, can be reached on (571)272-0787.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

April 10, 2007